

REMARKS

Claims 124-140 are pending in the application. Claims 128-134 are withdrawn by the examiner. Claims 124-127 and 135-140 are currently under examination. Claims 124-127 and 135-137 are amended by replacing the term "quenching" with "reducing" and to recite "reducing residual free radicals" for clarity, as discussed herein. Claim 125 also is amended for clarity to recite "cooling the preform after the heating step to a temperature below the melting temperature of the irradiated UHMWPE", as discussed herein. No new matter is introduced. The office action is discussed below:

Response to Amendment:

On pages 2-3 of the Office Action, the examiner has made comments on the amendment filed on October 15, 2010.

With respect to the support for the amendment to claim 124, applicants thank the examiner for finding correct pages 18 and 20 containing disclosures that UHMWPE is irradiated to crosslink the UHMWPE polymeric chains, and heating the irradiated UHMWPE above the melting point so that there are substantially no detectable free radicals, followed by cooling the heated UHMWPE to room temperature.

The examiner however noted that the terminology "quenching residual free radicals" is not found; thus opined that heating to obtain a product having "substantially no detectable free radicals" should be used in the claims instead of the phrase "quenching residual free radicals". Applicants respectfully disagree with the examiner, and refer to the previous explanation regarding the term "quenching", which generally refers to the term "reducing", that is reducing residual free radicals in this case.

Applicants point out that claims are interpreted in view of the specification and one skilled in the art would appreciate the disclosure of various methods of reducing (quenching) residual free radicals. Thus, the recitation of "quenching residual free radicals" is fully supported by the specification. In this context, applicants request the examiner to consider the MPEP that:

Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the

English language. See MPEP §§ 707.07(g); 2111.01 (Rev. 6, September 2007).

However, for additional clarity, applicants amend claims 124-127 and 135-137 by replacing the term "quenching" with the term "reducing" and to recite "reducing residual free radicals".

Withdrawal of Anticipation Rejection:

On page 2 of the Office Action, the examiner has distinguished the claimed invention and states that "Shalaby et al [US 5,824,411 patent] do not mention heating the irradiation crosslinked UHMWPE." Applicants thanks the examiner for the withdrawal of the alleged anticipation rejection of claims 124-127 in view of Shalaby (US 5,824,411 patent).

Response to Arguments and Rejections Maintained:

Written Description and Enablement Rejections:

On pages 5-7 of the Office Action, the examiner maintains the rejection of claims 124-127 and 135-140 under 35 U.S.C. 112, first paragraph, allegedly for failing to comply with the written description requirement. For instance, the examiner alleges that "a disclosure that UHMWPE is heated above the melting temperature for about 30 minutes to about 2 hours does not provide antecedent basis for claim language "pre-heating" UHMWPE to a "temperature greater than ambient temperature and less than the decomposition temperature of the UHMWPE for a period of time greater than 30 minutes" in claim 124". In addition to the previous explanation on page 6 of the response filed on October 15, 2010, applicants submit that additional support for the recited claimed steps can be found throughout the specification, for example, see Examples 16-20, on pages 60-73. More specifically, for example, see Example 18, at page 65 that describes:

"Eighteen pucks, 18 aluminum holders and 18 20cm x 20cm fiberglass blankets were preheated to 125°C, 90°C, or 70°C, in an air convection oven overnight. Six pucks were used for each different pre-heat temperature."

Clearly, there are disclosures of pre-heating of UHMWPE to a temperature greater than ambient temperature and less than the decomposition temperature of the UHMWPE.

With respect to the term "ambient temperature", applicants provided clarification pointing out that the specification refers to "room temperature", which essentially refers to the same environment. In order to advance the prosecution, applicants amend the claims by replacing the term "ambient temperature" with "room temperature".

With respect to the claim language of "heating the irradiated UHMWPE", on page 4 of the Office Action, the examiner intends that the claims be limited to recite "free radicals can be eliminated"..."by heating the UHMWPE above the melting point" as described in the specification page 14.

Although various process of heating is described throughout the specification, the examiner is trying to limit the claims to certain embodiments, for example, a process of heating above the melting point. This is not permissible. In this context, applicants request the examiner to consider the MPEP § 2111 that:

"The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, [70 USPQ2d 1827] (Fed. Cir. 2004)."

With respect to claim 125, the examiner also could not find any disclosure of the recited cooling after the quenching step "to a temperature below the melting temperature of the polyethylene". The examiner states, what is disclosed is cooling to room temperature after the step of heating irradiated UHMWPE to above the melting temperature to provide "substantially no detectable free radicals". Apparently, the examiner did not consider that the quenching step involves heating, which reduces detectable free radicals. Again, the examiner is trying to limit the claims to certain embodiment of the specification (such as described at page 18), which is not permissible. Applicants point out that the specification at page 18 discloses cooling step after heating irradiated UHMWPE.

Applicants submit that the examiner's interpretation of the claims 124-127 in view of certain aspects of the specification (such as pages 14, 20 and 21) and to limiting the claims to those aspects of the invention is not permissible. In this context, applicants also request the examiner to consider the MPEP that:

Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (Rev. 6, September 2007).

Claims must be "given their broadest reasonable interpretation consistent with the specification." See the Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005); *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow). See also MPEP § 2111 (Rev. 6, September 2007).

With respect to claims 135-137, the examiner states that a step for obtaining "substantially no free radicals" is disclosed in the specification on pages 14 and 21-22, wherein methods including the instantly claimed pre-heating are disclosed, i.e. "CIR" and "WIR" methods, which requires heating the irradiated UHMWPE above the melting temperature of the UHMWPE.

The examiner states that there is no disclosure of the recited heating the irradiated UHMWPE preform to a temperature "above ambient temperature" to "quench" free radicals or of a "quenching step".

Applicants refer to above explanation for additional support for the recited claimed steps, which can be found throughout the specification, for example, see Examples 16-20, on pages 60-73. More specifically, for example, see Example 20, at page 70 that describes:

"Following the irradiation, three pucks out of each different absorbed dose level were heated to 150°C for 2 hours to completely melt the crystals and reduce the concentration of free radicals to undetectable levels."

In view of the above clarifications and amendments to the claims, applicants request withdrawal of the written description rejection.

Enablement Rejection:

Regarding the enablement rejection and the "quenching" step, applicants refer to the explanation submitted on pages 9-10 of the response filed on October 15, 2010. In addition, applicants refer to above clarification and amendment to claims 124-127 and 135-137 by replacing the term "quenching" with the term "reducing" and to recite "reducing residual free radicals".

Accordingly, withdrawal of the enablement rejection is solicited.

Sequence of steps in the instant method claims:

The examiner opines that the method disclosed should be clearly set forth in the instant claims. Applicants believe, claims recite all required steps for one skilled in the art to be able to practice the invention in view of the specification, and are as clear as issued U.S. Patent No. 6,562,540, from which the claims were originally based. However, without acquiescing in the rejection, in order to expedite the prosecution, applicants amend the claim 124 to clarify that the method step of "reducing residual free radicals in the crosslinked UHMWPE preform by heating the irradiated UHMWPE."

Obviousness Rejection:

On pages 4-5 and 8 of the Office Action, the examiner has maintained the alleged obviousness rejection of claims 124-127 and 135-137 in view of Sun (the '049 patent).

According to the examiner, Sun et al specifically teach quenching free radicals remaining after irradiation by heat treatment followed by cooling (refers to column 6, lines 48-51, and column 8, lines 11-20). Applicants disagree with the examiner and point out that Sun does not suggest quenching of free radicals nor heating of a medical preform (see col. 6, lines 18-56). Sun suggests a post sterilization step of heating of packaged product (see col. 8, lines 11-20 and Abstract).

The examiner has misunderstood Sun process as a medical implant comprising annealing a medical implant and then radiation sterilizing the implant (refers to column 5, lines 38-67, and column 6, lines 42-43). The irradiated implant is then further

annealed to reduce free radicals (refers to column 6, lines 48-51). In fact, Sun's annealing step refers to heating prior to irradiation and a post sterilization heating of a packaged medical implant. Thus, Sun's heating step does not teach the claimed step of "reducing residual free radicals in the crosslinked UHMWPE preform by heating the irradiated UHMWPE."

Therefore, Sun does not make the claimed methods obvious. Accordingly, withdrawal of the obviousness rejection is solicited.

Double Patenting Rejection:

On pages 5 and 8-11 of the Office Action, the examiner also has maintained the provisional rejection of claims 124-127 and newly rejected claims 135-140 under the judicially created doctrine of obviousness-type double patenting allegedly as being unpatentable over various pending claims of co-pending Application Serial Nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089 and 10/197,263.

Because applicants have not received any notice of allowance for any of the cited co-pending applications, the merits of this provisional rejection need not be discussed by the examiner at this time. See MPEP § 822.01, more specifically, see MPEP § 804 I.B.

Between Copending Applications-Provisional Rejections

Occasionally, the examiner becomes aware of two copending applications that were filed by the same inventive entity, or by different inventive entities having a common inventor, and/or by a common assignee, or that claim an invention resulting from activities undertaken within the scope of a joint research agreement as defined in 35 U.S.C. 103(c)(2) and (3), that would raise an issue of double patenting if one of the applications became a patent. Where this issue can be addressed without violating the confidential status of applications (35 U.S.C. 122), the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting. *In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976); *In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966). The merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue.

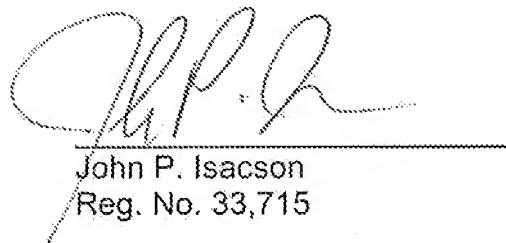
The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

Accordingly, the provisional double-patenting rejection over the co-pending U.S. Application Serial Nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089 and 10/197,263 should be withdrawn.

REQUEST

Applicants submit that claims 124-127 and 135-140 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 434-1610 should there be any questions.

Respectfully submitted,



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Date

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